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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/727,317 | 12/03/2003 | Akito Ichida | Furuya Case 1410 | 6210 |

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

| EXAMINER | |
|---|---|
| OH, TAYLOR V | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1625 | |

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/727,317 | ICHIDA, AKITO | |
| | Examiner | Art Unit | |
| | Taylor Victor Oh | 1625 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *22 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

***Final Rejection***

**The Status of Claims**

Claims 1-5 are pending.

Claims 1-5 have been rejected.

**Claim Rejections-35 USC 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of Claim 5 has been withdrawn due to the modification made in the amendment. However, there is still some issue to be resolved in Claim 5.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, the phrase " reducing 3-chloro-5-nitrotoluene obtained by the process " is recited. This expression is improper because it does not explain the essential step of the reduction as to how 3-chloro-5-nitrotoluene is reduced in order to obtain 3-chlroro-5-methylphenylisocyanate under any reagent and any temperature. Therefore, an appropriate correction is required.

**Claim Rejections-35 USC 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of Claims 1-2 under 35 U.S.C. 102(b) as being anticipated clearly by Grella et al (J. Med. Chem. P. 4726-4737, 2000) has been withdrawn due to the modification made in the amendment.

The rejection of Claims 1-2 and 5 under 35 U.S.C. 102(b) as being anticipated clearly by Chankvetadze et al (J. of Chromatography A, 787, (1997) p. 67-77) has been withdrawn due to the modification made in the amendment.

***Claim Rejections - 35 USC § 103***

1. Applicants' argument filed 11/22/04 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

***The rejection of Claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Grella et al (J. Med. Chem. P. 4726-4737, 2000) in view of Metzger (U.S. 3,972,910) .***

The rejection of Claims 1-4 under 35 U.S.C. 103(a) as being unpatentable over Grella et al (J. Med. Chem. P. 4726-4737, 2000) in view of Metzger (U.S. 3,972,910) has been maintained for the reasons of the record on 8/24/04.

**Applicants' Argument**

2. Applicants argue the following issues:

1. None of Grella et al and Chankvetadze et al do not teach the use of t-butylhypochorite or maintaining the reaction mixture at a temperature from 40 to 50 $^{0}$ C during deamination step ;

2. Metzger does not suggest the use of the chlorinating agents disclosed in the process of the Grella et al ;

3. Grella et al does not disclose the deamination temperature range of from 40 to 50 $^{0}$ C;

4. The present invention results in an unexpected improvement in high production yield of the product in comparison with the Grella et al process.

The applicants' argument have been noted, but these arguments are not persuasive.

First, with respect to the first and third arguments, the Examiner has noted applicants' argument. However, the secondary Metzger prior art does teach the use of the t-butylhypochorite. Therefore, the Metzger prior art does cure the deficiency of the Grella et al . On the other hand, the Chankvetadze et al is not used for the obviousness type against the claimed invention; therefore, it is irrelevant to the claimed argument.

With respect to the deamination temperature, Grella et al has expressly indicated that after adding sodium nitrite to the reaction mixture , the deamination is conducted between zero and room temperature and then the mixture is refluxed. With the Grella's et al guidance, it is possible that ,during the deamination process, the reaction mixture has been allowed to have the temperature variations of 40 to 50 $^{0}$ C. Furthermore, The limitation of a process with respect to ranges of pH, time and temperature does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the

process. Temperature is well understood by those of ordinary skill in the art to be a result-effective variable, especially when attempting to control selectivity in a chemical process. Therefore, it would have been obvious to the skilled artisan in the art to be motivated to optimize the deamination temperature range by a routine experimentation in order to attempt to control selectivity in the Grella's et al process.

Second, with respect to the second argument, the Examiner has noted applicants' argument. However, Metzger expressly teaches that the chlorination of the aminotoluene ring can be achieved either by N-chlorosuccinimide or t-butylhypochorite (see col. 2 ,lines 43-51). Similarly , Grella et al expressly teaches the preparation of 3-chloro-5-nitrotoluene by reacting 2-methyl-4-nitroaniline with the N-chlorosuccinimide chlorinating agent. From this, there is a teaching of equivalence between N-chlorosuccinimide and t-butylhypochorite. Furthermore, both prior art have been dealt with the chlorination of the aromatic compound with the substituents of methyl and amino groups. With the guidance of the Metzger teaching, therefore, it would have been obvious to the skilled artisan in the art to be motivated to employ Metzger's t-butylhypochorite as an alternative to the N-chlorosuccinimide chlorinating agent in the Grella et al process because the skilled artisan in the art would expect such a modification to be effective and successful as shown in the Metzger.

Third, with respect to the four argument, the Examiner has noted applicants' argument. However, the claim is directed to the process for preparing 3-chloro-5-

nitrotoluene ; there is no side-by-side comparison with respect to the unexpected result between the Grella et al prior art process and the currently claimed invention; therefore, applicants' mere argument about the unexpected result is of little value. The Examiner recommends applicants to file the Declaration regarding the unexpected result with the proper comparison between them. Until then , the rejection is to be maintained.

## *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

2/5/05

Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600